FDA 510(k) Premarket Notification

K233602 P200TE (A10700)

CLEARED

May 9, 2024
182 days to decision

K233602 · Product code: **OBO** · Ophthalmic
Source: https://www.510kdatabase.net/k233602/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Nov 9, 2023
Decision date	May 9, 2024
Days to decision	182 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Optos Plc.**
Location	Washington, DC, US
Contact	Graham McLeod
Website	http://www.optos.com/
510(k) history	15 submissions · 15 cleared · 1999-2024

Optos Plc. is a leading developer of ultra-widefield retinal imaging systems for eyecare professionals. The company specializes in innovative diagnostic devices that capture panoramic retinal images in a single shot. Now part of Nikon Corporation, Optos continues to operate as a distinct brand with a manufacturing facility in Washington, US. Optos has an established FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions. All submissions focus on Ophthalmic devices. The company's first clearance was in 1999, with the most recent clearance in 2024, d...

CLINICAL EVIDENCE - NCT05844852

P200TE US Reference Database Study

Status	Unknown - *No results published to ClinicalTrials.gov*
Enrollment	800 patients (estimated)
Study sites	9 sites
Condition studied	Normal Eyes
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	May 1, 2024
Sponsor	Optos, PLC (Industry)

Primary outcome

Retinal Thickness

Secondary outcome

Adverse Events

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05844852